UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION _____ **WAVE 1 CASES LISTED IN EXHIBIT A TO DEFENDANTS' MOTION**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **Joseph R. Goodwin** **UNITED STATES DISTRICT JUDGE**

DEFENDANTS JOHNSON & JOHNSON AND ETHICON, INC.'S REPLY IN SUPPORT OF MOTION TO EXCLUDE ANNE M. WEBER, M.D.

Much of Plaintiffs' response is spent touting Dr. Weber's experience and expertise in urogynecology generally. Ethicon did not challenge Dr. Weber's general expertise in the area of urogynecology, but rather, argued that she exceeded the bounds of her expertise in offering opinions about the Prolift device, a device which she has never used, never received any education or training on, and which only came on the market after Dr. Weber stopped performing surgeries. Her testimony should be excluded in the entirety. Alternatively, if she is permitted to testify at all, Dr. Weber's opinions should be sharply limited.

ARGUMENT

A. Dr. Weber's opinions should be limited to those articulated by Plaintiffs in their response brief.

Dr. Weber's opinions have been a moving target. Her 285-page single-spaced expert report covers an array of subjects, without any summary of opinions or table of contents.

In their response brief, Plaintiffs claim that Dr. Weber's opinions in this case are "narrower" because Dr. Daniel Elliott covers the issues of design defect and failure to warn. They state that Dr. Weber's opinions consist of:

- A discussion of the relative risks and benefits of the various alternative procedures for the treatment of POP, and that there was no need for the Prolift, and that the alternative procedures are safer alternatives;
- The results of and opinions flowing directly from her painstaking analysis of the raw clinical data, and governing protocols, for the prototype clinical studies conducted by and relied on by Ethicon to support the marketing of the Prolift, including significant discrepancies between her findings and the results reported by Ethicon;
- The results and opinions flowing directly from Dr. Weber's careful analysis of the data from the Ethicon-funded independent investigator study ("IIS") database, compiling the outcomes of over 500 patients treated by Dr. Vincent Lucente, who is one of the principal investigators for the Prolift prototype studies, a key Ethicon advocate and the author of numerous articles based on the IIS data (which grossly exaggerate the safety and efficacy of the Prolift, as uncovered by Dr. Weber's objective, scientific assessment of Dr. Lucente's data); and
- Dr. Weber's opinion, based on the clinical data, the medical literature and further supported by Ethicon's own internal documents and deposition admissions that the Prolift did not have an acceptable risk/benefit profile.

[Doc. 2182, pp. 2-3]. This is still not a precise description of Dr. Weber's opinions, as the phrase "results of and opinions flowing directly from" is hopelessly vague.

Later in their response brief, Plaintiffs state that "Dr. Weber's opinions will be consistent with the testimony she recently offered during the *Hammons v. Ethicon* trial in December 2015" and then proceed to list the following opinions:

- Prolift has an unacceptable risk/benefit profile due to high recurrence and erosion rates in the clinical data, 25:1-26:22;
- Dr. Weber analyzed the raw patient-level data (the only expert ever to do so), and found that the data underlying the Gynemesh PS mesh study does not support the reported 80-90% success rate claimed by Ethicon, 27:4-31:22;
- Dr. Weber analyzed the raw patient-level data (the only expert ever to do so), and found that the French TVM Study, relied on by Ethicon, was flawed and unreliable because there was a protocol deviation by including patients with Stage II prolapse in study, 33:18-34:18; and due to improper POP-Q measurement techniques, 36:11-37:17;

- The reported results of the French TVM study were flawed because they did not include women who reported complications at the 6-month interval if the same women did not return at the 1-year interval, 38:17-40:2;
- The French TVM study demonstrates, when corrected, an unacceptable risk/benefit profile (20.7% mesh exposure rate at the 1-year interval, which is a failure under Ethicon's own standard), 41:10-42:11, compare 47:7-48:25 (in another clinical mesh trial, the clinicians halted a study at the 3-month interval when complication rate reached 15.6%); (attached hereto as Ex. G).
- The US TVM mesh exposure study, when the data is correctly reported, also shows an unacceptable risk/benefit profile, 45:21-47:1;
- Dr. Weber is the only expert to review the IIS database, and found that the clinical data in the database funded by Ethicon, and compiled by Dr. Vincent Lucente (an Ethicon investigator and key opinion leader), demonstrates an unacceptable risk/benefit profile, 60:25-61:13; and that the Abstract presented by Dr. Lucente to the International Urogynecological Association ("IUGA") did not accurately report the results in his IIS database – downplaying recurrence and erosion rates and relying on an improper POP-Q technique, 51:22-58:6;
- Ethicon's Clinical Expert Report for the Prolift – which was a medical report written by Dr. Owens to justify sale of the Prolift, relies in part on the foregoing studies and data, and medical literature – is not supported by sufficient clinical data to establish the device is safe and effective for widespread marketing, 62:2-64:7;
- The Lowman article (relied on by Ethicon) regarding dyspareunia is unreliable because the authors based their analysis on medical charts (16.7% reporting pain with sex) rather than the women-patients' questionnaires (39% reporting pain with sex), 64:16-65:8, 72:8-73:2;
- A medical article authored by the TVM group shows unacceptably high complication rates (33.6%) at a short interval (3.5 months), 73:7-75:5;
- The September 2006 Abstract presented by the French TVM group shows at short-range follow-up a significant number of complications – especially to sexual function of younger women, 75:12-77:16;
- Ethicon marketed Prolift to all patients including those with only Stage I and II prolapse, but the TVM French group showed the device was only suitable for Stage III and IV prolapse, 77:23-79:13;
- The June 2009 IUGA presentation by members of the French TVM group analyzing contraction problem (19.6%) and related scar plating, which ultimately results in vaginal distortion, demonstrate an unacceptable risk/benefit profile, 79:17-87:22;

- Dr. Weber's 2007 ACOG Bulletin on mesh devices and opinion that mesh kits like Prolift present significant risks, and should have been, and be, considered "experimental," 87:25-91:22,93:14-99:6.

[Doc. 2182, pp. 5-6].

Ethicon has struggled mightily to determine precisely what Dr. Weber's opinions even are so that they can be adequately assessed under *Daubert* and Rule 702. It is the promise of Rule 26 that it should not be so in federal litigation.

It is not the job of Ethicon or the Court to parse hundreds or thousands of pages of expert reports and testimony to determine what Dr. Weber's opinions will be in these cases. Plaintiffs should be taken at their word, and Dr. Weber's opinions should now be limited to those articulated on pages 5-6 of Plaintiffs' response brief.

B. Dr. Weber is not qualified to offer opinions concerning the Prolift device.

Plaintiffs reduce Ethicon's challenges to Dr. Weber's qualifications to heuristics that do not accurately present the arguments: *e.g.*, "Rule 702 does not require a medical license to be qualified" and "Rule 702 does not require Dr. Weber to implant a Prolift to be qualified." [Doc. 2182, p. 7-13].

These statements miss the point. Ethicon has not moved for Dr. Weber's exclusion simply because she no longer has a medical license or because she has not implanted a Prolift. Rather, the point is that she surrendered her medical license *before* the Prolift was even on the market and has not engaged in any continuing medical education or training or clinical experience since that time to gain "knowledge, skill, experience, training, or education" on the device *except* in her capacity as a paid expert witness. *See* Fed. R. Evid. 702. Dr. Weber's opinions are not based on the "knowledge, skill, experience, training, or education" garnered in her practice, but rather are largely based on Dr. Weber's review of internal Ethicon documents as an expert witness.

Plaintiffs rely heavily on internal documents and deposition testimony where Ethicon's employees have acknowledged Dr. Weber's expertise. But Ethicon has not challenged here Dr. Weber's expertise in urogynecology generally, but more specifically, her opinions about the Prolift device. Dr. Weber's wide-ranging opinions about Prolift are not founded in her knowledge, skill, experience, training, or education and should be excluded.

C. Dr. Weber's opinions are unreliable and inadmissible.

In their response brief, Plaintiffs concede that Dr. Weber will not be offering opinions on direct examination concerning a number of subjects: degradation [Doc. 2182, p. 14], the Johnson & Johnson Credo [Doc. 2182, p. 16], Ethicon's state of mind [Doc. 2182, p. 16], ethics opinions [Doc. 2182, p. 16], the failure to report issues to the FDA [Doc. 2182, p. 17], and inflammatory language [Doc. 2182, p. 19]. Defendants file this reply to address several remaining subjects.

1. Dr. Weber's design opinions are not reliable.

Plaintiffs agree that Dr. Weber will not opine about degradation, but then state that her "methodology regarding the design of the Prolift and its characteristics is based on her clinical experience and relevant literature, as detailed in her extensive report." [Doc. 2182, p. 14]. But as noted in Ethicon's moving brief, Dr. Weber does not have clinical experience with the Prolift. *See, e.g., Tyree v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5486694, at *47 (S.D. W. Va. Oct. 29, 2014). And simply citing to an article is not reliable methodology where there is literature to the contrary not taken into account. *See In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005).

2. Dr. Weber's pre-market testing opinions are without reliable basis.

As described in Ethicon's moving brief, in order for Dr. Weber to fault Ethicon for failing to conduct certain testing, she must be able to cite to some standard showing that such testing was required. In response, Plaintiffs claim that Dr. Weber can offer this opinion because of her experience in designing and conducting clinical trials. Yet the question here is not about the design or conduct of clinical trials, but whether clinical trials were required.

In her expert report, Dr. Weber states that her opinion concerning the pre-market assessments of Prolift is "based upon analysis, from a medical perspective, of the evaluation by the medical affairs director who was tasked with this responsibility, Charlotte Owens, and the failure by the succeeding medical directors to remedy these medical evaluation flaws." Weber Report, p. 14. In other words, it is simply based on Dr. Weber's personal criticisms of the internal evaluations, and not based on any objective evidence or standard. But a company's internal standards are not sufficient to establish a standard of care. *See* 65 C.J.S. *Negligence* §66 ("violation of a company's rules is not negligence in and of itself"). In fact, if they exceed the standard of care they should not even be admitted into evidence. *Cast Art Industries LLC v. KPMG LLP*, 416 N.J. Super. 76, 106 (2010) ("such rules must be excluded, as a matter of law, if they requires a standard of care which transcends the traditional common-law standard"); *McHugh v, Jackson*, 2010 U.S. Dist. Lexis 18827 *6 n.4 (D. N.J. 2010) ("the standard of care is not generally measured by provisions in internal guidelines").

Absent any independent source for her standard of care, Dr. Weber's opinion should be excluded.

3. Dr. Weber's should not be permitted to offer opinions about improper informed consent.

It is unclear if Plaintiffs concede that Dr. Weber will not offer opinions criticizing the informed consent process for study participants. In their response, Plaintiffs agree that Dr.

Weber will not offer "ethics" opinions. [Doc. 2182, p. 16]. But then they go on to say that Dr. Weber "is clearly qualified to opine regarding the proper standards and protocols for informed consent in clinical trials, if asked." *Id*.

Dr. Weber's critique of the informed consent process for Ethicon studies is a purely ethical matter that has no bearing on the claims at issue in these cases. Thus, to the extent they are offered here, these opinions should be excluded.

4. Dr. Weber's opinions about improper physician training are irrelevant and unreliable.

Plaintiffs' argument does nothing to address the basic fact that Ethicon cannot control who uses their devices. The entire premise of Dr. Weber's "improper selection" of physicians opinion is fundamentally flawed.

This opinion is irrelevant if neither Dr. Weber nor any other of Plaintiffs' experts claim that the improper selection caused harm. In their response brief, Plaintiffs seek to turn the tables, arguing that if *Ethicon* argues physician error, then this opinion is relevant. [Doc. 2182, p. 18]. But even if physician error were at issue, this does not necessarily mean that the error was due to the physician's lack of qualifications. And it certainly does not mean that the result would have been different if Ethicon had declined to train the doctor, when Ethicon had no power over whether the doctor could use the device. Plaintiffs' argument is without merit, and the opinion should be excluded.

5. Dr. Weber's use of terms such as "guinea pig," "test subject," "epidemic," or "ticking time bomb" to refer to mesh or women implanted with mesh should be prohibited.

Plaintiffs state that Dr. Weber will not use inflammatory language, but their response demonstrates precisely why an order prohibiting Dr. Weber from using such terms as "guinea pig," "test subjects," "epidemic," or "ticking time bomb" is necessary.[1]

In their response, Plaintiffs claim that "contrary to defendants' rhetoric -- the terms 'epidemic' and 'test subject' are clearly, scientific terms." [Doc. 2182, p. 19]. But that was precisely Ethicon's point. Dr. Weber is using scientific terminology in an unscientific way, which should not be permitted. Dr. Weber has not performed a scientific analysis to determine that there is, scientifically speaking, an "epidemic" (even if she were qualified to do so, which Ethicon does not concede). Similarly, Dr. Weber well knows what a "test subject" truly is in the realm of scientific research, which the women implanted with Prolift were not.

Dr. Weber should not be permitted to offer these jury arguments under the guise of expert testimony. Any statement about "guinea pigs," "test subjects," "epidemics," or "ticking time bombs" should be excluded.

CONCLUSION

For these reasons, and those stated in Ethicon's motion and memorandum in support, Ethicon respectfully requests that Dr. Weber's testimony be excluded in its entirety.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

[1] Curiously, Plaintiffs criticize Ethicon for relying on statements Dr. Weber provided in her expert report in *this case* as opposed to citing her previous trial testimony in other cases, stating that this "objection is a non-issue." [Doc. 2182, p. 19]. Ethicon cannot rely on Dr. Weber's prior trial testimony in other cases for assurance that she will not offer opinions here consistent with her report.

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
Christy D. Jones

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